

Global Pulmonary Arterial Hypertension (PAH) Market: Analysis By Drug Class (Prostacyclin and Prostacyclin Analogs, Endothelin Receptor Antagonists (ERAs), sGC Stimulators, and pde-5 Inhibitors), By Type (Branded and Generic), By Route of Administration (Oral, Intravenous/ Subcutaneous, and Inhalation), By Distribution Channel (Hospital Pharmacies and Clinic, Retail Pharmacies, and Online Pharmacies), By Region Size and Trends with Impact of COVID-19 and Forecast up to 2028

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Abstracts

The global pulmonary arterial hypertension market was valued at US\$8.18 billion in 2022. The market value is expected to reach US\$11.43 billion by 2028. Pulmonary arterial hypertension (PAH) is a rare and progressive disorder characterized by elevated blood pressure of more than 25mmHg in the arteries of the lungs, also known as the pulmonary artery. While PAH affects both genders, it is more prevalent among females aged 30-60 years. Unfortunately, there is no known cure for PAH, but various treatment options are available to manage symptoms and enhance patients' quality of life.

The prevalence of PAH has been increasing over the years, which is contributing to the market growth. It is estimated that 37,000 patients are suffering from PAH in the US in 2022, and a similar number outside the US. Females are more likely to develop PAH, with a female-to-male ratio of 3:1. There are multiple approved drugs to treat PAH, but all are focused on improving hemodynamics in patients and not treating the underlying disease. New drug candidates target novel pathways that look to address the cause of

the disease. On the other hand, therapeutic options for pulmonary arterial hypertension (PAH) have increased over the last decades. The advent of pharmacological therapies targeting the prostacyclin, endothelin, and NO pathways has significantly improved outcomes. The development of new and improved therapies for PAH has expanded treatment options and improved patient management. Also, there have been advancements in the understanding of the underlying mechanisms of PAH, leading to the development of targeted therapies that provide better symptom control and disease management. The market is expected to grow at a CAGR of approx. 6% during the forecasted period of 2023-2028.

Market Segmentation Analysis:

By Drug Class: The report provides the pulmonary arterial hypertension market analysis based on the following drug class: Prostacyclin and Prostacyclin Analogs, Endothelin Receptor Antagonists (ERAs), sGC Stimulators, and pde-5 Inhibitors. The prostacyclin and prostacyclin analogs segment held the highest share in the market, whereas the sGC stimulator is expected to be the fastest-growing segment in the forecasted period. The most commonly used prostacyclin analogs are epoprostenol, treprostinil, and iloprost. The demand for prostacyclin analogs is increasing as these drugs have demonstrated significant efficacy in improving exercise capacity, reducing symptoms, and delaying disease progression in PAH patients. Their ability to target multiple aspects of the disease makes them valuable treatment options. On the other hand, sGC stimulators are often used in combination with other PAH-specific drugs, such as endothelin receptor antagonists and prostacyclin analogs, to achieve additive or synergistic effects. The main sGC stimulator currently approved for PAH treatment is riociguat.

By Type: The report provides the bifurcation of the market based on the following types: Branded and Generic. The branded drugs held the highest share of the market, as pharmaceutical companies invest significant resources in discovering and developing new drugs with novel mechanisms of action, improved efficacy, and better safety profiles. Generic drugs are expected to be the fastest-growing segment in the forthcoming years as they are generally less expensive than their branded counterparts and undergo regulatory scrutiny to ensure their safety, efficacy, and quality. As healthcare costs continue to rise, the affordability of generic drugs makes them an attractive option for many individuals and organizations.

By Route of Administration: The report provides an analysis of the PAH market based on the following route of administration: Oral, Intravenous/ Subcutaneous, and

Inhalation. The oral segment captured the highest share of the market in 2022, whereas intravenous/ subcutaneous is anticipated to be the fastest-growing segment in the upcoming years. The oral route is convenient for patients as it allows self-administration without the need for healthcare professionals or specialized equipment. This convenience can improve patient compliance and adherence to the prescribed treatment regimen. Whereas, intravenous/ subcutaneous is particularly important for PAH patients in critical condition or during acute exacerbations.

By Distribution Channel: The report offers a glimpse of the PAH market based on the following distribution channel: Hospital Pharmacies and clinics, Retail Pharmacies, and Online Pharmacies. Hospital pharmacies and clinic held the highest share of the market and is expected to be the fastest-growing segment in the forthcoming years. PAH patients may require hospitalization for acute exacerbations, diagnostic procedures, or specialized interventions. In such cases, hospital pharmacies play a crucial role in providing immediate access to medications needed for treatment and monitoring.

By Region: The report provides insight into the pulmonary arterial hypertension market based on the regions, namely, North America, Europe, Asia Pacific, Latin America, and Middle East & Africa. North America held the highest share of the market. In the US, most private health insurance plans in the US cover the treatment of PAH, including medications, diagnostic tests, and medical services. The availability of reimbursement and insurance coverage for PAH drugs plays a crucial role in driving demand. Additionally, many major pharmaceutical companies, including United Therapeutics, Bayer, Pfizer, etc., involved in the development, manufacturing, and commercialization of PAH drugs are based in the US or have a significant presence in the country. These companies have played a crucial role in advancing the understanding and treatment of PAH, thus contributing to market growth in the US.

Germany is a leader in medical research and innovation. Academic institutions, research centers, and pharmaceutical companies in Germany actively engage in PAH research, clinical trials, and the development of innovative therapies. The country's robust research infrastructure and collaborations between academia and industry contribute to advancements in PAH treatment, driving market growth.

Asia Pacific region is expected to be the fastest-growing region in the projected period. According to World Health Organization, China has one of the fastest-growing aging populations in the world. The population of people over 60 years old in China is projected to reach 28% by 2040, due to longer life expectancy and declining fertility rates. PAH is more prevalent among older adults, and as the population ages, the

incidence and prevalence of PAH naturally increase. In India, hospitals and medical centers are now equipped with state-of-the-art facilities, including cardiac catheterization labs and specialized units for pulmonary hypertension. This enhanced infrastructure enables the accurate diagnosis and appropriate management of PAH, contributing to the growth of the PAH market.

Market Dynamics:

Growth Drivers: The global pulmonary arterial hypertension market growth is predicted to be supported by numerous growth drivers such as a rising number of female populations, increasing healthcare expenditure, increasing research and development spending, rising prevalence of PAH, availability of reimbursement, and many other factors. PAH is more common in women than in men. Idiopathic PAH and heritable PAH are at least two and a half times more common in women than in men. Females of childbearing age are also more susceptible. It tends to affect females between the ages of 30 and 60, and the risk of developing the condition increases with age. The prevalence of PAH is expected to increase with the increasing number of older female population, hence leading to market growth.

Challenges: However, the market growth would be negatively impacted by various challenges such as strict regulatory standards, high development costs, limited treatment options, etc.

Trends: The market is projected to grow at a fast pace during the forecast period, due to various latest trends such as new potential drug development, recent advancements in treatment, technological advancements, increasing generic drugs, increasing awareness and diagnosis of PAH, automated fluid handling systems with machine learning, etc. Despite significant progress in PAH therapeutics over the last 2 decades, innovative treatments are needed to ameliorate morbidity and mortality in this progressive deadly disease. Beyond the current arsenal of treatments, BMP signaling, tyrosine kinase signaling, BRD proteins, sex hormones, and other more novel approaches such as gene therapy targeting pulmonary vascular remodeling are in varied stages of development. The development of new medications is expected to drive market growth.

Impact Analysis of COVID-19 and Way Forward:

COVID-19 had negatively affected the growth of the global pulmonary arterial hypertension market in the initial period of 2020, but as the restrictions eased, the

market growth rates came back to the trajectory. In 2021, the market experienced positive growth. The pandemic has led to delays in the diagnosis and treatment of many diseases, including PAH. Additionally, the pandemic caused disruptions in global supply chains, leading to shortages of some PAH medications and increased costs for drug manufacturers. However, many healthcare providers have shifted towards virtual consultations and remote monitoring of patients, which has led to greater convenience and improved access to care for PAH patients. This trend is expected to continue even after the pandemic subsides, as it provides a cost-effective and efficient way to provide ongoing care and support to patients.

Competitive Landscape:

The global pulmonary arterial hypertension market is moderately concentrated. The key players in the global pulmonary arterial hypertension market are:

Bayer AG

Pfizer Inc.

Johnson & Johnson

Novartis AG

Gilead Sciences, Inc.

Merck & Co., Inc.

GlaxoSmithKline Plc.

TEVA Pharmaceutical Industries Limited

United Therapeutics Corporation

Keros Therapeutics, Inc.

Liquidia Corporation

Reviva Pharmaceutical Holdings, Inc.

Resverlogix Corp.

Tenax Therapeutics

Aerovate Therapeutics, Inc.

Some of the strategies among key players in the market are new launches, investment in clinical development programs, mergers, acquisitions, and collaborations. Merck (MRK) is strengthening the company's PAH portfolio with Sotatercept. Merck acquired Sotatercept through its acquisition of Acceleron in 2021. Sotatercept is the first PAH drug to be granted Breakthrough Therapy Designation by FDA or PRIME designation by European Medicines Agency (EMA). On the other hand, United Therapeutics' Ralinepag is a novel oral IP receptor agonist which is undergoing placebo-controlled Phase 3 trials (Advance Outcomes and Advance Capacity) to determine its effect on time to clinical worsening and exercise capacity.

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